

REMARKS

The Rejection under 35 U.S.C. §102

The rejection of claims 9, 11-15, 31 and 32 under 35 U.S.C. §102, as being anticipated by Maesen (Eur.Respir.J.), is respectfully traversed.

As stated in the Office action, Maesen discloses the use of tiotropium bromide as a bronchodilator for patients with COPD. But the claims recite a “method for treating an inflammatory component of a disease selected from cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis” by administering a formulation comprising a salt of tiotropium. There is no explanation provided in the Office action as to how a method for treating COPD would anticipate a method for treating cystic fibrosis, idiopathic lung fibrosis or fibrosing alveolitis and, particularly, an inflammatory component thereof. In the absence of any disclosure of a method of treating the diseases as recited in the claims, there is no anticipation. Thus, the rejection under 35 U.S.C. §102 should be withdrawn.

The Rejection under 35 U.S.C. §103

The rejection of claims 9, 11-23 and 25-32 under 35 U.S.C. §103, as being obvious over Maesen, as applied above, further in view of Skupin (U.S. Patent No. 5,250,286) and Hochrainer (U.S. Patent No. 6,150,418), is respectfully traversed.

Maesen is relied on in this rejection for the same reasons as in the anticipation rejection. Applicants refer to their remarks above distinguishing the claimed invention from Maesen. The Skupin and Hochrainer references are relied upon for their teachings regarding the use of certain excipients in connection with active agents administered by inhalation. It is alleged that it would have been obvious to use the excipients taught by Skupin and/or Hochrainer together with the tiotropium active in the method taught by Maesen and such

would produce the claimed invention.

For the reasons pointed out in traversing the anticipation rejection, applicants urge that carrying out the method of Maesen (with or without the excipients taught in Skupin and/or Hochrainer) will not produce or suggest the claimed invention. Maesen teaches only a method for treating COPD and fails to teach or suggest a “method for treating an inflammatory component of a disease selected from cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis.”

Since the combination of reference teachings would not meet or suggest all elements of the claims, the combination of references fails to render the claimed invention obvious to one of ordinary skill in the art.

Additionally, applicants submit that there is insufficient reasoning for one of ordinary skill in the art to combine the reference teachings in the manner suggested in the Office action. Skupin teaches the use of certain excipients in connection with particular alpha-adrenergic blocking agents. Hochrainer teaches the use of certain excipients in connection with the particular beta-2-stimulator formoterol. Neither of the references provide any reason for one of ordinary skill in the art to reasonably expect that the excipients taught therein would also be useful in combination with a tiotropium salt anticholinergic. The active compounds used in Skupin and Hochrainer are completely distinct from tiotropium both in structure and activity. The Office action states that there was motivation to make the combination because Maesen teaches that tiotropium bromide is an effective bronchodilator. Applicants fail to see how such a teaching motivates the combination of tiotropium bromide with the excipients taught by the secondary references. Maesen only motivates use of the active agent for treating COPD, which does not result in or suggest the claimed invention.

For all of the above reasons, it is urged that the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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